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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/578,849	05/26/2000	Michael Z. Martin	031727.0001A	7983

25227 7590 10/15/2003
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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 10/15/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/578,849

Applicant(s)

MARTIN ET AL.

Examiner

Francisco C Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 99-121 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 99-119 is/are allowed.
- 6) ☒ Claim(s) 120-121 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 23
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The amendment filed July 31, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 99-121 are pending and are examined on the merits.

Drawings

This application contains a significant number of allowable claims. Although review of the transmittal letter for this application states that the drawings filed May 26, 2000, are considered formal, they are of extremely poor quality, extremely difficult to interpret, and are therefore considered to be informal. While the poor quality of the drawings did not preclude full examination of the application, applicant is advised that should this application be passed to issue, formal drawings of proper quality will be required.

Claim Rejections - 35 USC § 102/103

Claims 120 and 121 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Lopez-Avila et al (J. High Resol. Chromatogr. 20:555-559 (1997)).

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The reference discloses products which appear to be identical to the products recited in the claims as amended, based on the fact that the prior art products are relatively purified mixtures of the same compounds, kava lactones, produced by the same preparative process, supercritical fluid chromatography, from the same plant material, kava. See, e.g. page 556, disclosing the various fractions from the columns disclosed in the reference; see also page 557, disclosing the chromatograms from said columns. Consequently, the claimed products appear to be anticipated by the reference.

However, even if the reference products and the claimed products are not one and the same and there is, in fact, no anticipation, the reference products would, nevertheless, have rendered the claimed products obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that one of ordinary skill would expect the products of Lopez-Avila to differ somewhat because of batch-to-batch variations between kava source materials prepared at different times, under different conditions, as well as normal process variation due to expected experimental variations due to human error. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

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All of applicant's argument has been noted to the extent it applies to this new ground of rejection required by applicant's amendment. As amended, the claims no longer read on purified kava lactones. However, the claims as amended do read on fractions from kava containing those lactones. There is nothing on the record to suggest that the fractions obtained using isopropylamine-containing solvents are any different than the fractions obtained by Lopez-Avila, or that the products made by Lopez-Avila could not be prepared by the process recited in claim 120. In short applicant provides no evidence demonstrating a difference between the fractions obtainable by the claimed process, and fractions obtained by Lopez-Avila.

Applicant urges that amending claim 120 to be of comparable scope to allowed claim 99, combined with limiting the process to steps "consisting essentially of" those recited in the claim, renders that claim free of the prior art. However, again, applicant points to no evidence of record to demonstrate such a difference. On the current record, all that is known about the product-by-the-process recited in claims 120 and 121 is that it is a product that results from performing the claim-recited process. The sole example using an isopropylamine-containing solvent, appearing at page 40 of the specification, lines 23-26, and Fig. 29, demonstrates only that, when using a particular

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solvent and column combination, an isopropylamine-containing solvent provides a particularly good resolution of the kava lactones.

However, the products disclosed by Lopez-Avila contain all of the constituents which would result from performing supercritical chromatography on a mechanically disrupted kava material. There is simply no evidence currently of record suggesting that a process of the claimed scope results in a product any different than that disclosed by Lopez-Avila.

Moreover, the product-by-process claims are sufficiently broad to encompass the addition of even miniscule amounts, e.g. parts per billion, of isopropylamine to the solvent system of Lopez-Avila. The miniscule amounts of isopropylamine encompassed by applicant's claims would not be expected to affect the fractions obtained from Lopez-Avila's columns. Stated alternatively, on the current record it does not appear that by adding one part per billion of isopropylamine to the solvent system of Lopez-Avila, or any other prior art carbon dioxide/alcohol solvent system used to prepare kava extracts, the product would be in any way different. Rejection under §§ 102/103 is therefore clearly required in this instance.

Regarding the propriety of this type of alternative rejection, note that MPEP § 2113 states that:

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. . . [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP § 2113 also clearly states that

'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974)."

Claims 99-119 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

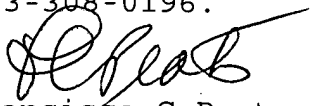
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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
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FCP